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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Woolcy	U022 1020.1	1163

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
	1615

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/955,657	WOOLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 5/19/04.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,2,5-15,18-22 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2,5-15,18-22 and 56-62 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 05/19/04.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

**Acknowledgment of Papers Received:** Request for Continued Examination filed 5/19/04 and Information Disclosure Statement filed 5/19/04.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 2, 5, 21, 22, 56-62 are rejected under 35 U.S.C. 102(a) as being anticipated by Raad et al (USPN 6,165,484 hereafter ‘484). The claims are drawn to a method of treating a bacterial infection by administering a composition consisting of a chelating agent, pharmaceutical carrier and an antimicrobial agent.

3. The ‘484 patent discloses compositions comprising chelating agents (EDTA), and antimicrobial agents (Table 2). The composition is used to treat fungal infections in the body (abstract; col. 20, lin. 23 – 62). The composition further comprises pharmaceutical carriers and is administered in various forms including oral suspension tablets, pills capsules, powders etc (col. 15, lin. 50 – col. 18, lin. 32). These disclosures render the claims anticipated.

4. Though the reference is silent to the particular steps of claims 2, 57 and 59, however it is the position of the examiner that these features would be inherent to the disclosures of the ‘484 patent. The claims recite steps of identifying a microbial population and determining concentration of chelators and antimicrobial agent suitable to fight the infection. The ‘484

teaches a composition where the chelator and antimicrobial agents in synergy (abstract), and the determinations of treatment and best modes of carrying out the invention would be evident to the practitioner of the invention. The identification of the microbial infection, and the treatment of such are inherent to the disclosures of the invention and therefor the reference anticipates the claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 6-9, 12-15, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484; and USPN 5,688,516 hereafter '516), and Kruse et al (USPN 5,646,151 hereafter '151). The claims are drawn to a method of treating a bacterial infection by applying a composition consisting of a chelating agent, antimicrobial agent and carrier.

8. As discussed above the '484 patent discloses a method for treating a bacterial infection comprising applying a composition comprising a chelating agent and an antimicrobial agent. What is lacking however is a disclosure of the particular antibacterial agents of the claims. The '516 patent discloses a method of treating Gram positive and negative bacterial infections by applying a composition of chelating agents such as EDTA and triethylene tetramine dihydrochloride and various anti-bacterial agents including oxytetracycline (col. 4, lin. 31 – 53; col. 5, lin. 37-53). The '151 patent discloses topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines (col.33, lin. 3-38; col. 34, lin. 25-48; col. 41, lin. 59-col. 43, lin. 54). The reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries topically. A skilled artisan would be motivated to include the chelating agents and antibiotics of '516 or '151 into the formulation of '484 in order to treat a wider range of bacterial infections.

9. Regarding claims 18-20 drawn to various skin injuries, the references disclose various well-known antibacterial/fungal agents, which are well known in the treatment of skin injuries. Though the references are silent to an ulcer specifically, it is the position of the examiner that the combination of chelators and biocides disclosed in the prior art would be sufficient in treating a bacterial infection wherever it would arise. It is the position of the examiner that these limitations do not impart patentability on the claims, barring a showing of criticality to the type of injury sustained. The examiner invites applicant to provide evidence of a criticality to the type of injury. Until such time, the claims will remain obviated by the prior art.

10. One of ordinary skill in the art would have been motivated to combine the TRIEN of '516 in order to import its copper chelating properties into the formulation. A skilled

artisan would be motivated to include the antimicrobial agents of '516 and '151 as well in order to treat a wider range of infections. It would have been obvious to a skilled artisan to combine these teachings and suggestions with an expected result of a method of treating a wide range of infections comprising applying chelating agents and antibacterial agents.

***Response to Arguments***

11. Applicant's arguments with respect to claims 1-55 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

All claims have been rejected, no claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young

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